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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,027	03/23/2004	Mark Edward Bunnage	PC9430B	4951

28523 7590 09/27/2004

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/808,027	Applicant(s) BUNNAGE ET AL.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/402,229.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' preliminary amendment, which involved cancellation of claims 1-21 and addition of new claims 22-23, filed on 3/23/ 2004 is made of record.

Claims 22-23 are now pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. US 5,955,611.

Dunn et al. teaches a process for making sildenafil which includes the use of orthohydroxy benzoic acid with piperazinyl sulfonamide group in 4- position with respect to the hydroxyl group as intermediate. See entire document especially formula I, II and

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III. Particularly see column 3-4 for a Scheme which teaches the process for making compound V which is same as claimed in the instant genus but excluded by the proviso in claim 22. Also note the process of acylation of the pyrazole VII with the said compound and subsequent cyclization to make sildenafil. See column 6-15 for examples 1-52 and preparations 1-7.

While said compound doesn't anticipate the scope of claim 22 in view of the proviso that when R³ is ethyl, R⁴ is not N-methylpiperain-1-yl-sulfonyl group, they are very closely related, being homologs of compounds i.e. ethoxy group on the phenyl ring in the reference instead of methoxy or propoxy group of instant genus. Similarly, the N-ethylpiperazin-1-yl-sulfonyl of instant genus is a homolog of is a homolog of N-methylpiperain-1-yl-sulfonyl group of the reference. However, homologs and compounds that differ only by CH₃ Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548.

Again, although said compounds do not anticipate the scope of claim 22, they are very closely related having R¹⁰ as a hydrogen group on the nitrogen of the piperazine group in the instant claims vs methyl on the nitrogen in the reference. However, compounds that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me on nitrogen, see *Ex parte Weston* 121 USPQ 428; *In re Doebl* 174 USPQ 156.

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Thus, one skilled in the art at the time of the invention would have been motivated to make homologs, and compounds that have H vs methyl on the nitrogen using the same process of making taught for the homolog and expect the process these compounds to possess the utility in the instant case as intermediates to make sildenafil analogs taught by the applied art in view of the close structural similarity outlined above.

Claim 22-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. US 5,272,147.

Bell et al. teaches several pyrazolopyrimidine compounds useful as antianginal agents, which include instant intermediate compound of claim 22 and the process. See column 1, formula 1, and note the definition of R^1 , R^2 , R^3 , and R^4 . Note the definition of the R^3 and R^4 groups overlap with instant R^3 and R^4 . See column 10 for the intermediate X, Especially see lines 4-32 which teaches the same process as that claimed in claim 23.

Bell et al., differs from instant claims in not showing examples of making the compound wherein R^4 is sulfonamide bearing a heterocyclic group.

However Bell et al. teaches the equivalency of exemplified compounds with various R^4 substituents with that claimed for formula I, See cols. 1, formula I, especially the definitions of R^3 and R^4 groups as noted above.

Thus, one having ordinary skill in the art at the time of the invention was made would have been motivated to make compounds variously substituted in phenyl ring and the intermediates using the process taught in column 10, lines as permitted by the

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reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Venkataraman Balasubramanian
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09/22/2004